4729:5-9-03.3 **Record keeping in an institutional facility.**

This rule applies to records for dangerous drugs, including those dispensed by an institutional pharmacy to inpatients, maintained in areas outside of the institutional pharmacy by an institutional facility.

(A) An institutional facility shall maintain a record of all dangerous drugs administered to patients that includes all the following information:

(1) Name of the patient;

(2) Name, strength, dosage form, route of administration, and quantity of the dangerous drugs administered;

(3) Date and time the dangerous drugs were administered;

(4) The positive identification of the person removing the dangerous drug for patient administration;

(5) Positive identification of the personnel administering the drug; and

(6) For controlled substance dangerous drugs:

(a) If removed from a secured location, the positive identification of the person removing the controlled substance for patient administration; and

(b) The disposal of an unused portion of a controlled substance conducted in accordance with paragraph (J) of rule 4729:5-9-03.2 of the Administrative Code.

(B) Records of dangerous drugs personally furnished at an institutional facility shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name, address and date of birth of the person to whom or for whose use the dangerous drug were personally furnished, the positive identification of the prescriber personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver.

(C) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt.

(D) Records of transfers to other terminal distributors of dangerous drugs, including sales conducted in accordance with rule 4729:5-3-09 of the Administrative Code, shall contain the name, strength, dosage form, and quantity of the dangerous drug

transferred, the address of the location where the drugs were transferred and the date of transfer.

(E) Records of temperature control monitoring described in paragraph (F) of rule 4729:5-9-03.2 of the Administrative Code shall include any of the following:

(1) For temperature logs, either:

(a) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or

(b) For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded.

(2) For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion.

(F) Records of dangerous drugs disposed from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, the positive identification of the licensed health care professional that performed the disposal.

(G) Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order issued by a prescriber or protocol authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of dangerous drugs shall be documented using positive identification. All orders for drugs for inpatients shall include the following:

(1) Name of patient;

(2) Name, strength, and dosage form of drug;

(3) Directions for use, including route of administration;

(4) Date prescribed; and

(5) The ordering prescriber's positive identification.

(H) Records of controlled substance drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.

(1) If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal, one of whom shall be the responsible person or the responsible person's designee.

(2) If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal.

(I) Controlled substance inventory records shall be maintained in accordance with rule 4729:5-3-07 of the Administrative Code.

(J) All records required in accordance with this chapter shall be maintained under appropriate supervision and control to restrict unauthorized access.

(K) All records maintained in accordance with this rule shall be readily retrievable and shall be kept on-site for a period of three years.

(1) A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board.

(2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(L) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) Complies with the requirements of this rule;

(2) All paper records shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user;

(3) Contains security features, such as unique user names and passwords, to prevent unauthorized access; and

(4) Contains daily back-up functionality to protect against record loss.

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